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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,742	10/22/1999	KARL THEODOR KRAEMER	02481.1641	9957

22852 7590 05/03/2002

FINNEGAN, HENDERSON, FARABOW, GARRETT &  
DUNNER LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/425,742

Applicant(s)

KRAEMER ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-29 are pending. Claim 9 is withdrawn from consideration, as it is directed toward non-elected subject matter.

#### ***Response to Applicant's Arguments/Amendment***

The Applicant's arguments filed March 21, 2002 (Paper No. 16) to the rejection of claims 1-8 and 10-29 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

#### ***103 Rejection Maintained***

The rejection of claims 1-8 and 10-29 under 35 U.S.C. 103(a) as being unpatentable over Claussner et al. (6,087,509) or Claussner et al. (5,750,553) in view of Cretois (5,558,859) in further view of Lai (5,916,910), Ismail (5,541,220), Galey et al. (WO 92/21317) Dumats (WO 91/19701), and Estradier et al. (EP 427625) is MAINTAINED for the reasons set forth in the Office Action mailed December 21, 2001, Paper No. 15, and those found below.

Applicant argues, "Conspicuously absent from the alleged motivation is any desirable reason to choose the specifically proposed ingredients (A) to (D) from the disparate references to form a single composition within the scope of the claims". This argument is not persuasive. Claussner and Claussner disclose that their active ingredient can be incorporated with excipients usually employed in compositions, such as aqueous or non-aqueous vehicles, gum, fatty substances of animal or vegetable origin, glycols, emulsifying agents, and others, and that their compositions can be in the form of solutions, suspensions, creams, ointments and lotions for topical application to the skin. Cretois discloses compositions for the treatment and protection of the exoskeletal parts. Cretois discloses polyhydroxylated castor oil as an emulsifying agent that

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is a fatty substance of vegetable origin, water as an aqueous vehicle, and vinylimidazolium methochloride/vinylpyrrolidone copolymer as a film-forming agent, wherein ointments and creams form films upon application. Additionally, Cretois discloses that antisebborrhoic agents can be added to her compositions, and the active agents of Claussner and Claussner are antisebborrhoic agents. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Cretois in formulating compositions for the active agents disclosed in Claussner and Claussner because of the expectation of forming antisebborrhoic compositions that comprise ingredients known to be safe for application to the skin, as disclosed by Cretois.

Applicant argues, “the genus of antisebborrhoic agents is too large to inherently describe every member within it”. This argument is not persuasive. First, the Examiner respectfully points out that MPEP 2144.08 II.A4a. is really directed to Markush claims wherein the genus of a compound is disclosed with a great number of variable groups. Second, the Examiner respectfully points out that a reference is relied upon for its teachings those of ordinary skill as a whole. In the instant case, Cretois discloses compositions that are safe for application to the skin that can contain antisebborrhoic agents. Since, Claussner and Claussner are directed toward topical application of antisebborrhoic agents, it would have been obvious to one of ordinary skill to look to Cretois for excipients that are safe for application to the skin.

Applicant argues, “Cretois teaches compositions for imparting good shape-retention to the hair, e.g., styling mousses, hair-setting lotions, and mascaras. . . What would motivate one of ordinary skill in the art to combine ingredients in a pharmaceutical composition with ingredients in a styling mousse, hair-setting lotion, or mascara”. This argument is not persuasive. The

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Examiner respectfully points out that a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507 (CCPA 1966). In re Chapman, 357 F.2d 418, 148 USPQ 711 (CCPA 1966). In Col. 1, Cretois discloses that her invention is directed to the use of compositions for a nonwashing treatment of the keratinous exoskeletal parts. For motivation, see above and see the Office Action mailed December 21, 2001, Paper No. 15.

Applicant argues, "if topical formulations of antiandrogen drugs such as those of Claussner-'509 and Claussner-'553 have been discouraged in the art then formulating a topical antiandrogenic drug would be contrary to accepted wisdom". This argument is not persuasive, as showings of facts are much preferred to statements of opinion. In re Oelrich, 198 USPQ 210, 215 (CCPA 1978). While Applicant has provided some articles that do teach the difficulty of topically applying antiandrogens, Applicant has provided no data showing why the antiandrogens of Claussner and Claussner are not effective when topically applied. If Applicant achieves results that are unexpected, the Examiner respectfully suggests that Applicant set forth a declaration of his unexpected results.

### ***Unexpected Results***

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing"

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*In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, there are no unexpected results.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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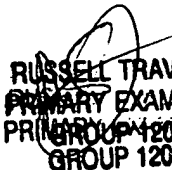
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

April 25, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200  
GROUP 1200